

Application No.: 08/999,752

Docket No.: TEVNHC 3.0-200

IN THE CLAIMS

1.-22. (canceled)

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23. (currently amended) A product suitable for delivering a pharmaceutical aerosol formulation comprising,

(a) an aerosol canister comprising a container closed with a metering valve, said container ~~further~~ comprising a pharmaceutical aerosol formulation substantially free of surfactant comprising,

(i) a bronchodilator selected from the group consisting of ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, repreoterol, rimiterol, salbutamol, salmeterol, terbutaline, isoetharine, tolubuterol and orciprenaline or a salt—thereof,— of said bronchodilator, wherein said bronchodilator is in particulate form; and

(ii) a fluorocarbon propellant; and

(iii) 6% to 25% of a polar co-solvent; and

(b) an actuator with a spray orifice aperture of from about 100 to about 300 microns;

~~wherein said canister fits into the actuator.~~

24. (previously presented) The product of claim 23, wherein the bronchodilator is substantially insoluble in the co-solvent.

25. (previously presented) The product of claim 23, wherein the bronchodilator is in the form of a salt.

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26. (previously presented) The product of claim 24, wherein the bronchodilator is in the form of a salt.

27. (previously presented) The product of claim 23, wherein the bronchodilator is a salt of salbutamol.

28. (canceled)

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29. (previously presented) The product of claim 23, wherein the canister is actuated by a breath operated device.

30. (previously presented) The product of claim 23, wherein the propellant is 1,1,1,2-tetrafluoroethane or 1,1,1,2,3,3,3-heptafluor-n-propane.

31. (new) The product of claim 23, wherein the bronchodilator is a salt of salbutamol.

32. (new) The product of claim 31, wherein the propellant is 1,1,1,2-tetrafluoroethane.

33. (new) The product of claim 31, wherein the polar co-solvent is ethanol.

34. (new) The product of claim 33, wherein ethanol is present in the amount of 10% to 15%.

35. (new) The product of claim 31, wherein the propellant is 1,1,1,2-tetrafluoroethane and the polar co-solvent is ethanol.

36. (new) The product of any of claims 31-35, wherein the salt of salbutamol is salbutamol sulphate.

37. (new) The product of claim 23, wherein the polar co-solvent is present in the amount of 10% to 15%.

38. (new) The product of claim 23, wherein the spray orifice aperture is from about 150 to about 250 microns.

39. (new) A product suitable for delivering a pharmaceutical aerosol formulation comprising,

(a) an aerosol canister comprising a container closed with a metering valve, said container comprising a pharmaceutical aerosol formulation substantially free of surfactant, and which comprises salbutamol sulphate, ethanol, and 1,1,1,2-tetrafluoroethane, wherein salbutamol sulphate is present in said formulation in particulate form and is substantially insoluble in the 1,1,1,2-tetrafluoroethane, and

(b) an actuator with a spray orifice aperture of from about 100 to about 300 microns.

40. (new) The product of claim 39, wherein the aerosol formulation contains salbutamol sulphate in the amount of 0.35% w/w.

41. (new) The product of claim 39, wherein the aerosol formulation contains ethanol in the amount of 10% w/w to 15% w/w.

42. (new) The product of claim 41, wherein the aerosol formulation contains ethanol in the amount of 11.41% w/w.

43. (new) The product of claim 39, wherein the aerosol formulation contains 1,1,1,2-tetrafluoroethane in the amount of 88.24% w/w.

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44. (new) The product of claim 39, wherein the aerosol formulation contains salbutamol sulphate in the amount of 0.35% w/w, ethanol in the amount of 11.4% w/w, and 1,1,1,2-tetrafluoroethane in the amount of 88.2% w/w.

45. (new) The product of claim 39, wherein the spray orifice aperture is from about 150 to about 250 microns.

46. (new) A product suitable for delivering a pharmaceutical aerosol formulation comprising,

(a) an aerosol canister comprising a container closed with a metering valve, said container comprising a pharmaceutical aerosol formulation substantially free of surfactant, and which consists of salbutamol sulphate, ethanol, and 1,1,1,2-tetrafluoroethane, wherein salbutamol sulphate is present in said formulation in particulate form and is substantially insoluble in the 1,1,1,2-tetrafluoroethane, and

(b) an actuator with a spray orifice aperture of from about 100 to about 300 microns.

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